



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 29 2004

Mr. Ron Teegarden
President
Dragon Herbs
315 Wilshire Boulevard
Santa Monica, California 90401

Dear Mr. Teegarden:

This is in response to your letter of September 1, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Dragon Herbs is making the following claims, among others, for the following products:

Pearl

"[B]eneficial for habitual constipation." Dietary Supplement in assisting the
"[C]an help lower blood pressure."

Duanwood Reishi

"[H]elp the body respond to microbial invaders such as viruses, bacteria and yeast."
"[H]elps lower HDL [sic] (the "bad" cholesterol)..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely hypercholesterolemia, hypertension, chronic constipation, and infectious diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

978-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

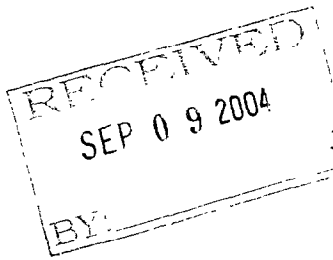
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



Dragon Herbs

315 Wilshire Blvd., Santa Monica, CA 90401
Tel: (310) 917-2288 Fax: (310) 917-1134

September 1, 2004

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling & Dietary Supplements
Food & Drug Administration (HFS-800)
5100 Paint Brush Parkway
College Park, Maryland 20740

SEP 20 2004

Ref: Notifications for 7 Dragon Herbs products

Dear Dr. Moore,

Attached please find notifications being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in these notifications. The notifications are being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93).

Notifications attached are being filed for the following products:

1. Duanwood Reishi – 100 capsules
2. Cordyceps – 100 capsules
3. Pearl– 100 capsules
4. Eleuthero – 2 fl. oz. extract
5. Natural Plant Extract Powder 50204-001– 1 kg (for further processing and packaging only)
6. Natural Plant Extract Powder 50204-002– 1 kg (for further processing and packaging only)
7. Natural Plant Extract Powder 50204-003– 1 kg (for further processing and packaging only)

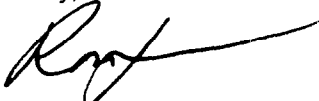
Labels of these products are hereby attached.

Please be advised that we have substantiation on file that these claims are truthful and not misleading.

Should your office have any questions, please do not hesitate to contact us immediately.

We are more than willing to provide additional information for your review and to revise any claims and statements that your office finds necessary for revisions.

Sincerely,


Ron Teeguarden
President of Dragon Herbs

89604-759

Dragon Herbs

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Tel: (310) 917-2288 Fax: (310) 917-1134
Ron Teegarden, President

SEP 20 2004

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 C.F.R. (101.93)

This notification is being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in this notification. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93). The dietary supplement on whose labeling the statements appear is "**PEARL**."

The principle display panel bears no structure/function statements. The panel does include the following DSHEA statement: "This product is not intended to diagnose, treat, cure or prevent any disease."

Labeling for this product other than the principle display panel bears structure/function statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The structure/function statements for which notification is now being given, which are based on credible third-party substantiation on file in our office, are:

- Pearl powder is an excellent source of bone-building calcium.
- Pearl powder may have a calming effect.
- Pearl powder may promote sound sleep.
- Pearl powder may help regenerate tissue.
- Pearl powder may clear toxins.
- Pearl powder may improve eyesight.
- Pearl powder may promote muscle development.
- Pearl powder may invigorate blood circulation.
- Components in pearl powder help maintain the health of the skin by participating in the metabolic activities of the skin.
- Pearl powder promotes the regeneration of new cells and makes the skin smooth, fine, elastic and naturally beautiful.
- Various components in pearl participate in DNA and RNA metabolic activities, and thus can promote and accelerate cell renewal.
- Pearl powder can promote the activities of the important natural antioxidant enzyme, SOD.
- Pearl powder can help prevent the development of melanin, which causes freckles and dark patches on the skin.
- Consistent use of pearl powder can eliminate blemishes such as colored spots and even pimples.
- Pearl powder, a rich source of calcium, has been shown in China to help the growth of children's teeth and bones.
- Pearl powder has been shown in China to improve children's intelligence.
- Pearl has also been shown to be beneficial for habitual constipation.
- Pearl can help lower blood pressure.
- Pearl helps increase endurance.
- Mucopolysaccharides in pearl powder have been shown to prevent wrinkling.
- Pearl can help prevent osteoporosis due to its high calcium content.

TRADITIONAL USES (referenced from standard Chinese herbal texts)

- Pearl is used as a *Shen* tonic used to stabilize the emotions, allay fright, and to ease frustration and anger.
- Pearl is used to brighten the eyes.
- It is believed that oral consumption of Pearl powder results in lustrous, pure, beautiful skin.
- Constant use can help assure that the skin will age more slowly and that it will not be easily harmed by either time or the elements.

Adjacent to all these statements is a ruled DSHEA statement: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

We have substantiation on file that these claims are truthful and not misleading.

Dragon Herbs

315 Wilshire Blvd., Santa Monica, CA 90401

Tel: (310) 917-2288 Fax: (310) 917-1134

Ron Teeguarden, President

SEP 20 2004

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 C.F.R. (101.93)

This notification is being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in this notification. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93). The dietary supplement on whose labeling the statements appear is "**Duanwood Reishi.**"

The principle display panel bears no claim statements. The panel does include the following DSHEA statement: "This product is not intended to diagnose, treat, cure or prevent any disease."

Labeling for this product other than the principle display panel bears structure/function statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The structure/function statements for which notification is now being given, which are based on credible third-party substantiation on file in our office, are:

- Reishi has anti-stress activity.
- Reishi may improve sleep.
- Reishi is an immune potentiator.
- Reishi has been found to improve the functioning of the immune system whether the immune system is deficient or excessive.
- Reishi is an immune "modulator"---that is, it helps to modulate, or regulate the immune system.
- Chemical constituents known as polysaccharides play an important role in strengthening the body's overall immune functions.
- The polysaccharides appear to help the body respond to microbial invaders such as viruses, bacteria and yeast.
- Ganoderic acids in Reishi inhibit histamine release, improve oxygen utilization and improve liver functions. Ganoderic acids are also potent antioxidant free-radical scavengers.
- Reishi may improve the physical condition of the cardiovascular system.
- Reishi helps lower HDL (the "bad" cholesterol) and reduce excess fatty acids.
- Reishi stimulates the production of interferon and interleukins I and II, potent natural immunity-boosting substances produced in our own bodies.

Adjacent to this statement is a ruled DSHEA statement: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

TRADITIONAL USES (referenced from standard Chinese herbal texts)

- Reishi tonifies Jing, Qi and Shen.
- Protects the entire body. Nurtures the Heart*, protects the Liver*.
- Historically Reishi was believed to help calm the mind, ease tension, strengthen the nerves, strengthen memory, sharpen concentration, improve focus, build will power and, as a result, help build wisdom.
- Reishi mushroom is revered in Asia as a tonic herb consumed for the attainment of radiant health, longevity and spiritual attainment.
- Reishi has traditionally been used as an anti-aging herb.
- The Chinese have traditionally claimed that Reishi promotes calmness, centeredness, balance, inner awareness and inner strength.
- Chinese monks and spiritual seekers have traditionally used Reishi to improve meditative practices and to protect the body, mind and spirit so that an adept could attain both a healthy and long life.

We have substantiation on file that these claims are truthful and not misleading.

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